THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Ream et al.
Appl. No.:	10/044,113
Filed:	January 9, 2002
Title:	OVER-COATED PRODUCT INCLUDING CONSUMABLE CENTER AND MEDICAMENT
Art Unit:	1618
Conf. No.	9176
Examiner:	Ahmed, Hasan Syed
Docket No.:	112703-201

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on November 6, 2008. This Appeal is taken from the Final Rejections in the Office Action dated August 6, 2008.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Wm. Wrigley Jr. Company by virtue of Assignments dated December 27, 2001 and January 9, 2002 and recorded at reel 012484, frames 0915-0918 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1-35 are pending in the above-identified patent application. Claims 1-7 and 21-35 were previously withdrawn from consideration. Claims 8-20 stand rejected. Therefore, Claims 8-20 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Non-Final Office Action was mailed on January 25, 2008. In the Non-Final Office Action, the Patent Office rejected the claims under 35 U.S.C. §§ 112, 102 and 103. Appellants filed a response to the Non-Final Office Action on April 21, 2008. A Final Office Action was mailed on August 6, 2008. In the Final Office Action, the Patent Office withdrew the rejections under 35 U.S.C. §§ 112 and 102 but maintained the obviousness rejection. Appellants filed a Notice of Appeal on November 6, 2008 with respect to the Final Office Action mailed on August 6, 2008. Copies of the Non-Final Office Action mailed on January 25, 2008 and the Final Office Action mailed on August 6, 2008 are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 8 recites a product (page 3, paragraphs 37-38) comprising a medicament (page 1, paragraph 3, lines 1-13; page 2, paragraph 29, lines 1-7; paragraph 31, lines 2-8; pages 4-5, paragraph 66, lines 6-15 and 21-31) comprising: a consumable tableted center (page 2, paragraph 19, lines 1-6; paragraph 24, lines 1-3; page 3, paragraph 54, lines 3-10; pages 3-4, paragraph 56, lines 3-11; page 4, paragraph 58, lines 3-17; paragraph 59, lines 1-8), wherein the consumable tableted center is not a chewing gum (page 3, paragraph 55, lines 6-8); and a coating (page 2, paragraphs 22-23; paragraphs 26-28; page 3, paragraph 33, lines 3-6; paragraphs 35-36; page 4, paragraph 61, lines 3-7; paragraph 62, lines 1-5; paragraph 64, lines 1-6; paragraph 66, lines 1-5; page 5, paragraph 75, lines 1-5; page 6, paragraph 78, lines 1-14; paragraph 80, lines 1-3 and 10-12) comprising the medicament, wherein said coating surrounds the consumable center (page 2, paragraph 21, lines 2-3; paragraph 30, lines 2-4; paragraph 32, lines 3-5; page 3, paragraph 33, lines 3-4; paragraph 34, lines 3-7; paragraph 54, lines 1-3; page 4, paragraph 57, lines 1-3; Fig. 1), the coating comprising at least 50% by weight of the product (page 2, paragraph 21, lines 3-5; paragraph 25; paragraph 32, lines 3-5; page 3, paragraph 33, lines 3-6; paragraph 54, lines 12-14; page 4, paragraph 61, lines 1-3).

Independent Claim 16 recites a product (page 3, paragraphs 37-38) comprising a medicament (page 1, paragraph 3, lines 1-13; page 2, paragraph 29, lines 1-7; paragraph 31, lines 2-8; pages 4-5, paragraph 66, lines 6-15 and 21-31) comprising: a consumable tableted center (page 2, paragraph 19, lines 1-6; paragraph 24, lines 1-3; page 3, paragraph 54, lines 3-10; pages 3-4, paragraph 56, lines 3-11; page 4, paragraph 58, lines 3-17; paragraph 59, lines 1-8), wherein the consumable tableted center is not a chewing gum (page 3, paragraph 55, lines 6-8); and a coating (page 2, paragraphs 22-23; paragraphs 26-28; page 3, paragraph 33, lines 3-6; paragraphs 35-36; page 4, paragraph 61, lines 3-7; paragraph 62, lines 1-5; paragraph 64, lines 1-6; paragraph 66, lines 1-5; page 5, paragraph 75, lines 1-5; page 6, paragraph 78, lines 1-14; paragraph 80, lines 1-3 and 10-12) comprising the medicament that at least substantially surrounds the consumable tableted center (page 2, paragraph 21, lines 2-3; paragraph 30, lines 2-4; paragraph 32, lines 3-5; page 3, paragraph 33, lines 3-4; paragraph 34, lines 3-7; paragraph 54,

lines 1-3; page 4, paragraph 57, lines 1-3; Fig. 1), the coating comprising at least 50% of the product by weight (page 2, paragraph 21, lines 3-5; paragraph 25; paragraph 32, lines 3-5; page 3, paragraph 33, lines 3-6; paragraph 54, lines 12-14; page 4, paragraph 61, lines 1-3).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the reference numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the reference numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 8-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,056,541 B1 to Stahl ("*Stahl*"). A copy of *Stahl* is attached herewith as Exhibit C in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged

from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

B. THE CLAIMED INVENTION

Independent Claim 8 recites, in part, a product comprising a medicament. The product comprises a consumable tableted center and a coating comprising the medicament. The consumable tableted center is not a chewing gum. The coating surrounds the consumable center and comprises at least 50% by weight of the product.

Independent Claim 16 is directed to a product comprising a medicament. The product comprises a consumable tableted center and a coating comprising the medicament. The consumable tableted center is not a chewing gum. The coating at least substantially surrounds the consumable tableted center and comprises at least 50% of the product by weight.

C. THE REJECTION OF CLAIMS 8-20 UNDER 35 U.S.C. §103(a) TO *STAHL* SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS NOT ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS

1. The claims require a consumable tableted center, wherein the consumable tableted center is not a chewing gum

Appellants respectfully submit that *Stahl* fails to disclose or suggest every element of the presently pending claims. Independent Claim 8 recites, in part, a product comprising a medicament comprising: a consumable tableted center, wherein the consumable tableted center is not a chewing gum; and a coating comprising the medicament, wherein said coating surrounds

the consumable center, the coating comprising at least 50% by weight of the product.. Similarly, independent Claim 16 recites, in part, a product comprising a medicament comprising: a consumable tableted center, wherein the consumable tableted center is not a chewing gum; and a coating comprising the medicament that at least substantially surrounds the consumable tableted center, the coating comprising at least 50% of the product by weight..

The product of the present claims causes a medicament to be released into the saliva of a consumer when the product is chewed. See, Specification, page 3, paragraph 55, lines 1-2. Furthermore, the continual chewing of the product builds up a pressure which forces the medicament through the oral mucosa and into the buccal cavity of the consumer, thereby providing an increased absorption and bioavailability of the medicament as compared with typical oral administration. See, Specification, page 3, paragraph 55, lines 3-7 and 13-20. However, unlike chewing gum, the consumable center is designed to dissolve in the mouth of the consumer and/or be swallowed. See, Specification, page 3, paragraph 54, lines 6-8. Moreover, by precisely controlling the size of the consumable center via tableting, one can provide a more accurate level of coating. See, Specification, page 4, paragraph 58, lines 11-17. In contrast, *Stahl* fails to disclose a consumable tableted center, wherein the consumable tableted center is not a chewing gum for at least the reasons set forth below.

2. *Stahl* does not teach or suggest a consumable tableted center, wherein the consumable tableted center is not a chewing gum

Appellants respectfully submit that *Stahl* fails to disclose or suggest a consumable tableted center, wherein the consumable tableted center is not a chewing gum as required, in part, by all of the independent Claims 8 and 16 and Claims 9-15 and 17-20 that depend therefrom. The Patent Office asserts that *Stahl* discloses a consumable tableted center in accordance with Claims 8 and 16. See, Final Office Action, page 2, lines 13-15. However, *Stahl* is entirely directed to a coated core of chewing gum. See, *Stahl*, Title; Abstract, lines 1-7; Column 1, lines 18-19. "The present invention relates to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material as well as one or more active substance(s)." See, *Stahl*, Column 1, lines 8-11. Nowhere does *Stahl* disclose or suggest that its core or consumable center is anything other than a chewing gum. In fact, the only references in *Stahl* to

a "tablet" both involve chewing gum. See, *Stahl*, Column 1, lines 36-39 ("A chewing gum with a completed coating is normally finally treated with a surface layer of a wax or the like. The tablets with a completed coating are then subjected to a hardening process"); Column 8, lines 61-63 ("In order to achieve a neat and smooth surface of the chewing gum tablets with the completed coating, these may subsequently be subjected to a polishing"). Moreover, *Stahl* repeatedly describes the "core" of its product as chewing gum. See, *Stahl*, Column 1, lines 18-24 and 65-66; Column 6, lines 19-22; Column 8, lines 3-4 and 24-27; Column 9, lines 8-10. As such, *Stahl* fails to disclose a consumable tableted center that is not a chewing gum.

The Patent Office nevertheless asserts that the innermost coating of *Stahl* can be a "consumable tableted center" within the meaning of the present claims. See, Final Office Action, page 4, lines 13-15. However, Appellants respectfully submit that a layer of coating cannot be a "consumable tableted center" because the claims and Specification clearly distinguish between a coating and a consumable tableted center. For example, independent Claims 8 and 16 recite, in part, a "consumable tableted center" and a coating which "surrounds" or "substantially surrounds the consumable tableted center." Because the claims require that the coating surround or substantially surround the consumable tableted center, the coating must be distinct from the consumable center. The Specification also states that "[a]s used herein 'consumable center' means that a center is provided that can be ingested by the consumer. . . . If desired, the center can be tableted. . . . This allows an accurate control of the coating." See, Specification, page 3, paragraph 54, lines 3-11. This passage also clearly distinguishes between the tableted center and the coating. As such, Appellants respectfully submit that it is improper to consider a layer of the coating to be a "consumable tableted center" within the meaning of the present claims.

Moreover, the innermost layer of coating disclosed by *Stahl* is not a "center" as required, in part, by the present claims. A "center" of an object is "a part of an object that is surrounded by the rest; a core." See, The American Heritage Dictionary (4th Ed. 2003), http://www.thefreedictionary.com/center. However, *Stahl* repeatedly emphasizes that its "core" is chewing gum, rather than the innermost layer of coating. See, *Stahl*, Column 1, lines 8-9, 18-19 and 65-67; Column 2, lines 3-15; Column 6, lines 19-23; Column 8, lines 3-4, 16 and 33-35; Column 9, lines 8-12. *Stahl* further states that the layers of coating are applied to the core. See, *Stahl*, Column 1, lines 19-23; Column 2, lines 12-20. Therefore, Appellants respectfully submit

that the coating cannot be part of the core and, thus, is not a "consumable tableted center" as required, in part, by the present claims.

Furthermore, Appellants note that the present Specification contemplates that the coating may comprise various layers. See, Specification, Claims 4, 24 and 30. For example, in describing the coating process, the Specification states "[t]his process is continued until the necessary amount of syrup and powder have been applied to the exterior of the center, e.g., 10 to 20 coating layers or more are applied." See, Specification, page 5, paragraph 76, lines 4-7. However, the Specification also makes it clear that the multiple layers of coating are applied to the "exterior of the center" and thus are not part of the center. Therefore, Appellants respectfully submit that a layer of coating is not a "consumable tableted center" in accordance with the present claims.

For at least the reasons discussed above, Appellants respectfully submit that *Stahl* fails to disclose every element of independent Claims 8 and 16 and Claims 9-15 and 17-20 that depend therefrom and, thus, that Claims 8-20 are novel, nonobvious and distinguishable from *Stahl* and are in condition for allowance.

Accordingly, Appellants respectfully request that the rejection of Claims 8-20 under 35 U.S.C. §103(a) be withdrawn. .

VIII. CONCLUSION

Appellants respectfully submit that the Patent Office has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejection of Claims 8-20. Accordingly, Appellants respectfully submit that the obviousness rejection is erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge $540 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-201 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

Dated: January 6, 2009

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/044,113

8. A product comprising a medicament comprising: a consumable tableted center, wherein the consumable tableted center is not a chewing gum; and a coating comprising the medicament, wherein said coating surrounds the consumable center, the coating comprising at least 50% by weight of the product.

9. The product of Claim 8 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

10. The product of Claim 8 wherein the coating includes a taste masking agent.

11. The product of Claim 10 wherein the taste masking agent is chosen from the group consisting of: zinc gluconate, glycine, acesulfame-k, aspartame; saccharin; fructose; xylitol; isomalt; maltitol; spray dried licorice root; glycerrhizine; sodium gluconate; glucono delta-lactone; ethyl vanillin; dextrose; sucralose; vanillin; and ethyl maltol.

12. The product of Claim 10 wherein the taste masking agent comprises approximately 30% to about 99% by weight of the coating.

13. The product of Claim 8 wherein the coating includes approximately 0.1% to about 5% by weight of a high-intensity sweetener selected from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

14. The product of Claim 8 wherein the consumable center is selected from the group consisting of hard confectionaries, gummi confectionaries, confectionary starches, and compressible excipients.

15. The product of Claim 8 wherein the coating does not have a shellac layer.

16. A product comprising a medicament comprising: a consumable tableted center, wherein the consumable tableted center is not a chewing gum; and a coating comprising the medicament that at least substantially surrounds the consumable tableted center, the coating comprising at least 50% of the product by weight.

17. The product of Claim 16 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

18. The product of Claim 16 wherein the consumable center is selected from the group consisting of hard confectionaries, gummi confectionaries, confectionary starches, and compressible excipients.

19.. The product of Claim 16 wherein a taste masking agent comprises approximately 30% to about 99% by weight of the coating.

20. The product of Claim 16 wherein the coating includes approximately 0.1% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action dated January 25, 2008

EXHIBIT B: Final Office Action dated August 6, 2008

EXHIBIT C: U.S. Patent No. 7,056,541 B1 to Stahl (*"Stahl"*), cited by the Patent Office in the Final Office Action dated August 6, 2008

RELATED PROCEEDINGS APPENDIX

None.

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176

29156 7590 01/25/2008
BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' RCE, amendment, remarks, and terminal disclaimers, all filed on 25 October 2007.
- The obviousness-type double patenting rejections are withdrawn in view of the terminal disclaimers.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 25 October 2007 has been entered.

* * * * *

Terminal Disclaimer

The terminal disclaimers filed on 25 October 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,355,265; 6,541,048; 6,426,090; 6,322,806; 6,290,985; 6,627,234; 6,465,003; 7,163,705; 6,773,716; 6,645,535; 6,558,692; and 6,355,265 as well as any patent granted on U.S. Application Nos. 09/990,628; 10/206492; 11/269,980; 11/273,941; and 11/273,942 have been reviewed and are accepted. The terminal disclaimers have been recorded.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, the instant claim set recites the limitation "wherein the consumable tableted center is not a chewing gum". After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. The specification, including page 10, lines 10-19 has been carefully reviewed and sufficient support for the limitation "wherein the consumable tableted center is not a chewing gum" was not found.

Importantly, the amendment absolutely excludes chewing gum from the claimed invention. There is no suggestion in the instant disclosure, either implicit or explicit, that chewing gum is to be excluded from the disclosure. To the contrary, the instant specification repeatedly discloses chewing gum as an embodiment of the application:

- instant claims 14 and 18 recite a consumable center comprising gummy confectionaries;

- the consumable center may comprise a gummi candy (*see* page 5, line 16);
- drug delivery is provided by, "...chewing the product to cause the medicament to be released from the product into the buccal cavity of the chewer; and continuing to chew the product thereby creating a fluid pressure causing the medicament to enter the systemic system of the chewer through the oral mucosa contained in the buccal cavity." *see* page 6, lines 22-26;
- an advantage recited by the instant application is, "...to provide a chewable product that contains an agent that heretofore could not be provided in a chewable form that was palatable." *see* page 8, lines 11-13; and
- example 1 (*see* instant specification, pages 22-25) and example 2 (*see* instant specification, pages 22-25) which are explicit examples of a consumable center comprised of chewing gum.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 8-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,541,048 to Zyck et al. ("Zyck").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Zyck teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 10, line 3);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 2, lines 18-23);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 10, line 29);
- the antacids of instant claims 9 and 17 (*see* col. 2, lines 18-23);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 8, line 55);
- the xylitol of instant claim 11 (*see* col. 8, line 55);
- the aspartame of instant claims 13 and 20 (*see* col. 7, line 49); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 1, line 65 – col. 2, lines 25-27).

Zyck does not disclose a shellac layer.

2. Claims 8-14 and 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,627,234 to Johnson, et al. ("Johnson").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnson teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 10, line 57);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 2, lines 59-66);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 15, line 41);
- the analgesics of instant claims 9 and 17 (*see* col. 5, line 65);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 12, line 38);
- the xylitol of instant claim 11 (*see* col. 12, line 38);
- the aspartame of instant claims 13 and 20 (*see* col. 9, line 27); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 2, lines 59-66).

3. Claims 8-14 and 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,163,705 to Johnson, et al. ("Johnson").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnson teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 13, line 51);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 3, lines 16-19);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 12, line 1);
- the muscle relaxants of instant claims 9 and 17 (*see* col. 5, line 9);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 13, line 66);
- the xylitol of instant claim 11 (*see* col. 13, line 66);
- the aspartame of instant claims 13 and 20 (*see* col. 13, line 17); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 3, lines 16-19).

4. Claims 8-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,645,535 to Zyck et al. ("Zyck").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Zyck teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 10, line 37);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 2, lines 33-44);
- the at least 50% coating by weight of instant claims 8 and 16 (see col. 9, line 9);
- the antacids of instant claims 9 and 17 (*see* col. 2, lines 33-44);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 9, line 17);
- the xylitol of instant claim 11 (*see* col. 9, line 17);
- the aspartame of instant claims 13 and 20 (*see* col. 8, line 13); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 2, lines 33-44).

Zyck does not disclose a shellac layer.

* * * * *

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,056,541 to Stahl ("Stahl").

Stahl teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 1, line 38);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 2, lines 37-49);
- the vitamins of instant claims 9 and 17 (*see* col. 5, line 17);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 7, line 21);
- the xylitol of instant claim 11 (*see* col. 7, line 21);
- the aspartame of instant claims 13 and 20 (*see* col. 5, line 10); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 1, line 65 – col. 2, line 2).

It would have been obvious to on having ordinary skill in the art at the time the invention was made to omit the shellac layer of instant claim 15, since it has been held that omission of an element and its function in a combination where the remaining

elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Stahl explains that adding a medicament to the coating is beneficial because, "...active substance(s) is/are exposed to the consumer within a short period of chewing." *See* col. 2, lines 52-53.

While Stahl does not explicitly teach the percentages of instant claims 8, 12, 13, 16, and 20, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a product comprising a consumable tableted center and a coating comprising a medicament, as taught by Stahl. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a product because it quick exposure of medicament to the consumer, as explained by Stahl.

* * * * *

Response to Arguments

Applicants' arguments filed on 25 October 2007 have been fully considered but they are not persuasive.

Applicants argue that the instant application is distinguished from the cited prior art by the newly added amendment, "wherein the consumable tableted center is not a chewing gum". *See* remarks, filed 25 October 2007.

The newly added amendment is deemed to be new matter and, as such is not given any patentable weight (*see* 35 USC 112, 1st paragraph rejection, above).

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

HUMERA N SHEIKH
PRIMARY EXAMINER

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	**Ronald L. Ream**	112703-201	9176

29156 7590 08/06/2008

BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' response, which was filed on 22 April 2008.
- The 35 USC 112 and 102 rejections are withdrawn in view of the remarks.

* * * * *

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,056,541 to Stahl ("Stahl").

Stahl teaches a product comprising a medicament comprising:

- the consumable tableted center of instant claims 8 and 16 (*see* col. 1, line 38);
- the coating comprising a medicament of instant claims 8 and 16 (*see* col. 2, lines 37-49);
- the vitamins of instant claims 9 and 17 (*see* col. 5, line 17);
- the taste masking agent of instant claims 10, 12, and 19 (*see* col. 7, line 21);
- the xylitol of instant claim 11 (*see* col. 7, line 21);
- the aspartame of instant claims 13 and 20 (*see* col. 5, line 10); and
- the gummi confectionaries of instant claims 14 and 18 (*see* col. 1, line 65 – col. 2, line 2).

It would have been obvious to on having ordinary skill in the art at the time the invention was made to omit the shellac layer of instant claim 15, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Stahl explains that adding a medicament to the coating is beneficial because, "...active substance(s) is/are exposed to the consumer within a short period of chewing." *See* col. 2, lines 52-53.

While Stahl does not explicitly teach the percentages of instant claims 8, 12, 13, 16, and 20, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a product comprising a consumable tableted center and

a coating comprising a medicament, as taught by Stahl. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a product because it quick exposure of medicament to the consumer, as explained by Stahl.

* * * * *

Response to Arguments

Applicants' arguments filed on 25 October 2007 regarding the 35 USC 103 rejection have been fully considered but they are not persuasive.

Applicants argue, "....*Stahl's* reference to "tablets" actually relates to forming a harder and a crunchy coating on a chewing gum." (Emphasis removed.) *See* remarks, page 5.

The "harder and crunchy" coating disclosed in Stahl is applied in multiple layers, the outermost having the active agent (*see* col. 2, lines 16-19). Instant claims 8 and 16 use the open transitional phrase "comprising." As such, a composition comprising a chewing gum and a consumable tableted center (the innermost coating), as that disclosed by Stahl, reads on the instant application, as claimed.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-7 and 21-35 drawn to an invention nonelected without traverse in the reply filed on 28 January 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618

EXHIBIT C

US007056541B1

(12) **United States Patent**
Stahl

(10) **Patent No.: US 7,056,541 B1**
(45) **Date of Patent: *Jun. 6, 2006**

(54) **COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF AND THE USE OF ONE OR MORE ACTIVE SUBSTANCE(S) IN SOLID FORM**

(75) Inventor: **Bronislaw-Jan Stahl**, Vejle (DK)

(73) Assignee: **Dandy A/S**, Vejle (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/623,425**

(22) PCT Filed: **Mar. 3, 1999**

(86) PCT No.: **PCT/DK99/00108**

§ 371 (c)(1),
(2), (4) Date: **Mar. 26, 2001**

(87) PCT Pub. No.: **WO99/44436**

PCT Pub. Date: **Sep. 10, 1999**

(30) **Foreign Application Priority Data**

Mar. 4, 1998 (DK) 0296/98

(51) **Int. Cl.**
A23G 3/30 (2006.01)

(52) **U.S. Cl.** **426/5**; 426/98

(58) **Field of Classification Search** 426/5, 426/89, 103, 285, 302, 303, 304, 305, 306, 426/658, 660, 98
See application file for complete search history.

(56) **References Cited**

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WO	WO 9308700	5/1993
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WO	WO 97/041662 A	2/1997
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WO	WO 9733485	9/1997
WO	WO 9814070	4/1998
WO	WO 98/23165	6/1998
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* cited by examiner

Primary Examiner—Keith Hendricks
(74) *Attorney, Agent, or Firm*—Hunton & Williams

(57) **ABSTRACT**

A coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substances in solid form. The use of an active substance in solid form in the coating of a coated chewing gum provides a fast onset of the effect, a better stability of the active substance, and an increased effect thereof in al chewing phases.

27 Claims, 14 Drawing Sheets

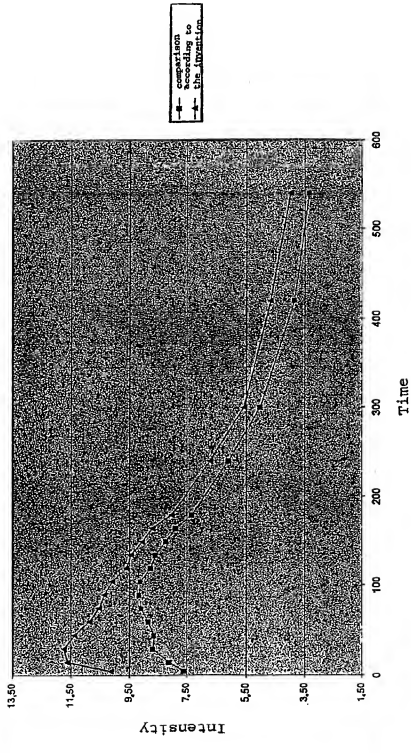
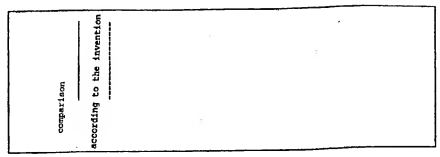

comparison
according to
the invention
Intensity
13,50
11,50
9,50
7,50
5,50
3,50
1,50
Time
0
100
200
300
400
500
600

Fig. 1


comparison
according to the invention

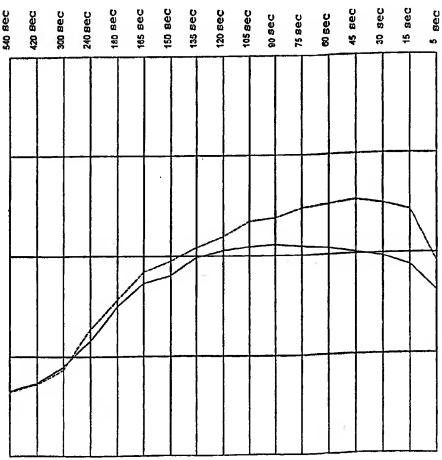

Time
540 sec
420 sec
300 sec
240 sec
180 sec
165 sec
150 sec
135 sec
120 sec
105 sec
90 sec
75 sec
60 sec
45 sec
30 sec
15 sec
5 sec
0
3,8
7,5
11,8
15
Intensity

Fig. 2

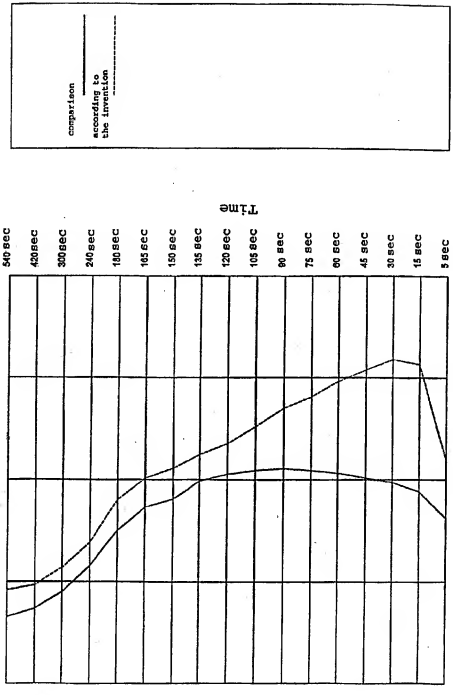

comparison
according to the invention
Time
540 sec
420sec
300sec
240 sec
180sec
165 sec
150 sec
135 sec
120 sec
105 sec
90 sec
75 sec
60 sec
45 sec
30 sec
15 sec
5 sec
0
3.8
7.6
11.3
15
Intensity

Fig. 3

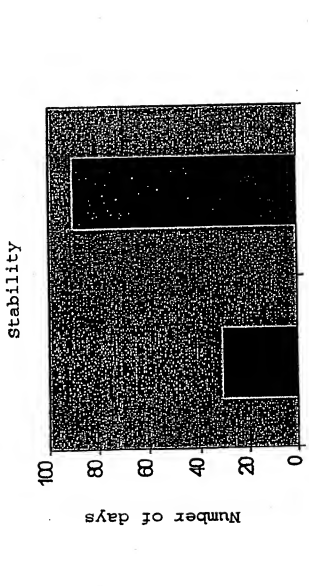

Stability
Number of days
100
80
60
40
20
0
Non-encapsulated aspartame
Encapsulated aspartame

Fig. 4

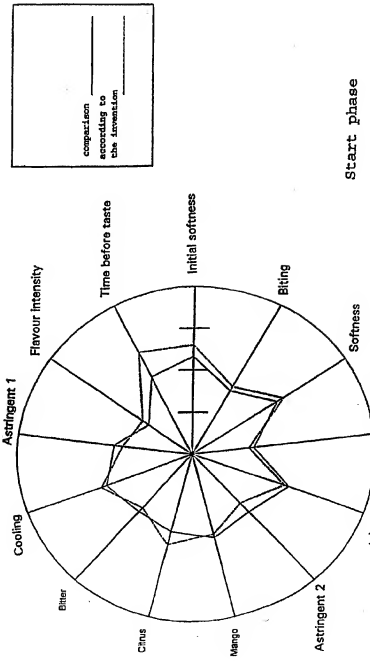

comparison
according to
the invention
Start phase
Initial softness
Biting
Softness
Sweetness
Juicy
Astringent 2
Mango
Citrus
Bitter
Cooling
Astringent 1
Flavour intensity
Time before taste
Scale
0
3,75
7,50
11,25
15

Fig. 5

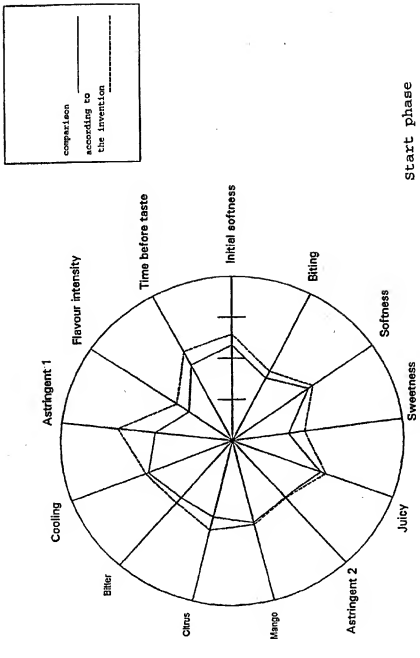

comparison
according to
the invention
Start phase
Initial softness
Biting
Softness
Sweetness
Juicy
Astringent 2
Mango
Citrus
Bitter
Cooling
Astringent 1
Flavour intensity
Time before taste
Scale :
0
3.75
7.50
11.25
15

Fig. 6

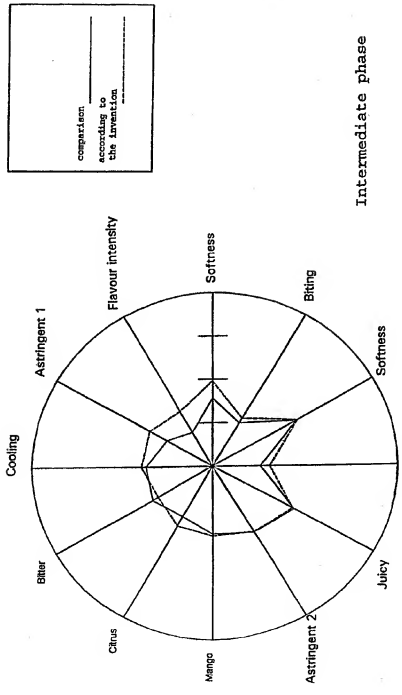

comparison
according to the invention
Intermediate phase
Flavour intensity
Softness
Biting
Softness
Sweetness
Juicy
Astringent 2
Mango
Citrus
Bitter
Cooling
Astringent 1
Scale:
0
3.75
7.50
11.25
15

Fig. 7

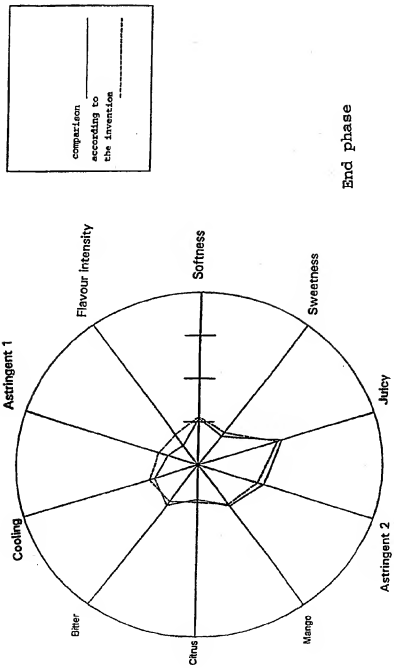
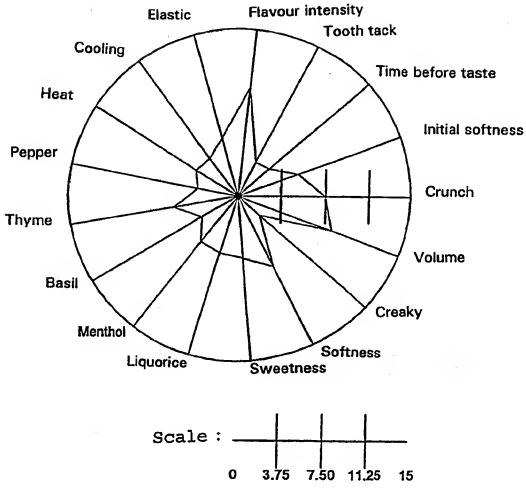
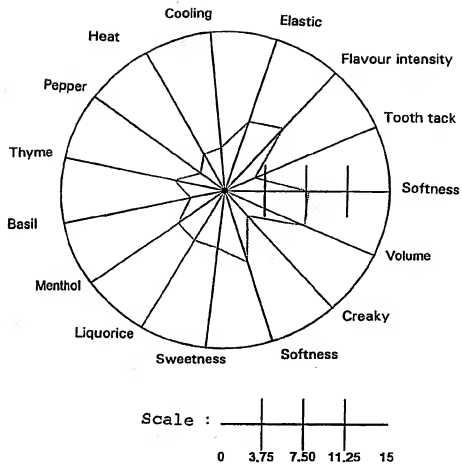

comparison
according to
the invention
End phase
Flavour intensity
Softness
Sweetness
Juicy
Astringent 2
Mango
Citrus
Bitter
Cooling
Astringent 1
Scale:
0
3.75
7.50
11.25
15

Fig. 8



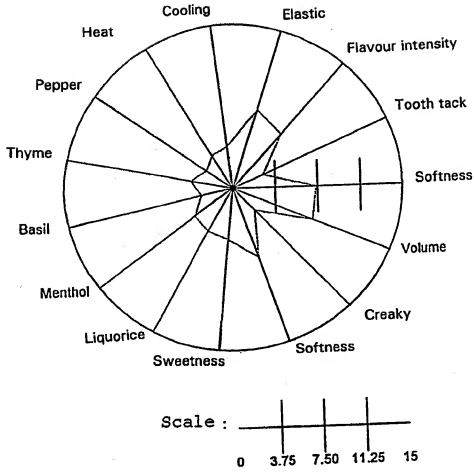
Start phase

Fig. 9



Intermediate phase

Fig. 10



End phase

Fig. 11

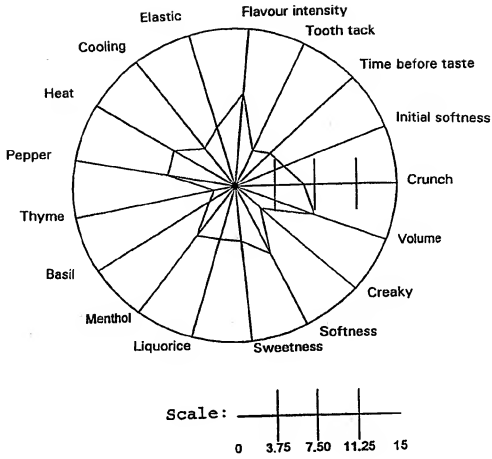
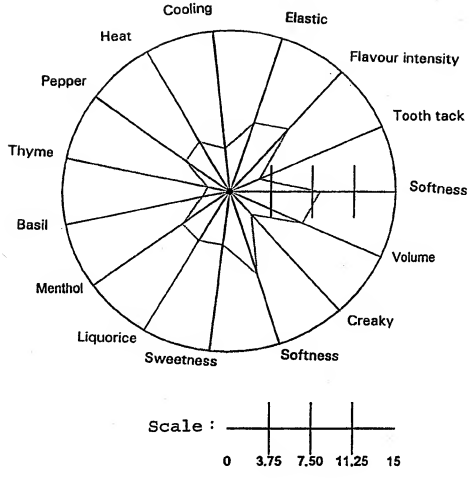
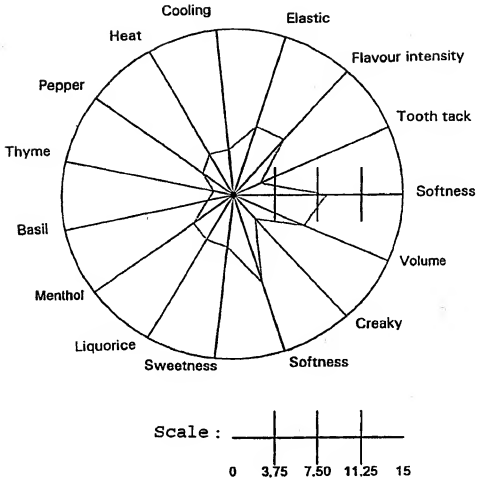

Elastic
Flavour intensity
Tooth tack
Cooling
Time before taste
Heat
Initial softness
Pepper
Crunch
Thyme
Volume
Basil
Creaky
Menthol
Softness
Liquorice
Sweetness
Scale:
0
3.75
7.50
11.25
15
Start phase

Fig. 12



Intermediate phase

Fig. 13



End phase

Fig. 14

COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF AND THE USE OF ONE OR MORE ACTIVE SUBSTANCE(S) IN SOLID FORM

TECHNICAL FIELD

The present invention relates to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material as well as one or more active substance(s) in solid form. Furthermore, the invention relates to a method for the preparation of a coated chewing gum and the use of one or more active substance(s) in solid form in the coating of a coated chewing gum.

TECHNICAL BACKGROUND

Coated chewing gum is prepared by coating a core of chewing gum with a number of layers of coating. The coating most often takes place in rotating coating kettles in which cores of chewing gum are rotated and coating suspension is applied in small portions that disperse evenly over the surfaces of the cores. Subsequently, the coated cores are dried by means of air.

These coating operations may be applied in up to approx. 90 increments until the preferred coating thickness is obtained, and the product has the preferred measures and the preferred weight.

The coating suspension is often an aqueous solution of a sugar or the like applied at an elevated temperature to ease the coating process.

In order to provide a fast flavour onset, often one or more flavour(s) is/are applied and possibly other active substances between the applications of the coating suspension. The active substance(s) is/are added in liquid form in one or more increment(s).

A chewing gum with a completed coating is normally finally treated with a surface layer of a wax or the like.

The tablets with a completed coating are then subjected to a hardening process during the following approx. 8 weeks. Sugar alcohols such as sorbitol and xylitol thus form crystals whereby the chewing gum obtains a harder and a "crunchy" coating. The crystallisation process also provides a more porous coating structure. Thus, a migration of water, moisture and flavour takes place through the formed micro channels.

This causes the chewing gum to gradually lose its flavour, ethereal oils, if any, are oxidised, and the chewing gum loses moisture and gets harder.

Furthermore, the use of active substances in liquid form in the coating layers has the disadvantage that some of the active substances are lost to the surroundings during the coating process.

It has now been found that by using active substances in solid form in the coating layers of conventional chewing gum, an increased stability of the active substance is obtained. Furthermore, a faster onset of the effect is achieved, and by using flavour in solid form, a longer lasting explosion of taste compared with chewing gum coated with a liquid flavour. Finally, according to the invention, a more environmentally desirable manufacturing process is obtained since the use of an active substance in solid form causes less evaporation of volatile substances.

DISCLOSURE OF THE INVENTION

Thus, the invention relates to a coated chewing gum comprising a core of chewing gum and a coating which comprises a coating material, and one or more active substance(s), which chewing gum is characterised in that the active substance(s) is/are added in solid form.

Furthermore, the invention relates to a method for the preparation of a coated chewing gum according to the invention, which method is characterised in that it comprises the following steps:

1) preparation of a core of chewing gum in a manner known per se,

2) preparation of a coating suspension, also in a manner known per se,

3) repeated applications of the coating suspension onto the cores of chewing gum also in a manner known per se, preferable at a temperature in the interval 30 90° C., preferably 35–75° C.,

4) Applying on the coating of one or more active substance(s) in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)

5) optionally, application of one or more liquid active substance(s) in one or more increments between the applications of the coating suspension,

6) optionally, finally application of a surface layer.

Applying of the solid active substance(s) is/are preferable performed without drying of the coating suspension in order to enable adherence of a substantial amount of the substance(s) in solid form to the coating. The drying time for the coating suspension depends on the specific coating formulation, however, the active substance(s) is/are added to the coated chewing gum substantially without delay after the coating processes are finished. If desired, the coated chewing gum may be wetted before adding the active substance(s) in solid form in case the coating has been allowed to dry for too long time whereby the coated chewing gum is no longer sticky.

The coating process may be repeated as many times as needed in order to obtain the desired thickness of the coating. In the coating process, the active substance(s) in solid form may be added between one or more of the ordinary coating processes. The last layer of the coating process may also include the active substance(s) in solid form. It is also within the present invention to use different active substances in solid form in the same coating layer or use one active substance in one layer, and a second active substance in another layer. Such combinations of active substances may be flavour and high potent sweeteners or a medicament together with an substance decreasing an undesirable taste of the medicament.

As the active substance(s) is/are located in the outer part of the coating, the active substance(s) is/are exposed to the consumer within a short period of chewing. Accordingly, in a further embodiment, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to obtain a fast onset of the effect.

A further advantage of the admixture of the active substance(s) in solid form is that the solid form is more resistant to decomposition. Accordingly, the invention also relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to obtain a better stability of the active substance(s).

Finally, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to obtain an increased effect of the active substance(s) in all chewing phases.

BRIEF DESCRIPTION OF THE DRAWING

The invention is further illustrated by means of the drawing, in which

FIG. **1** shows the release of flavour as a function of time by using menthol/anethol/eucalyptus flavour in encapsulated form and liquid form, respectively,

FIG. **2** shows the release of flavour as a function of time by using the same amount of eucalyptus/anethol/menthol flavour in encapsulated form and liquid form, respectively,

FIG. **3** shows the release of flavour as a function of time by using liquid eucalyptus/anethol/menthol flavour and with and without encapsulated menthol,

FIG. **4** shows the stability of chewing gum with apple/cinnamon flavour with encapsulated and non-encapsulated aspartame, respectively, in suspension form in the coating,

FIG. **5** shows a flavour profile in the initial phase of chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated citric acid in the coating,

FIG. **6** shows a flavour profile in the initial phase of a chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated "cooling agent" in the coating,

FIG. **7** shows the same in the intermediate phase,

FIG. **8** shows the same in the end phase,

FIG. **9** shows a flavour profile in the initial phase of chewing gum with menthol/anethol/eucalyptus flavour and with encapsulated thyme extract in the coating,

FIG. **10** shows the same in the intermediate phase,

FIG. **11** shows the same in the end phase,

FIG. **12** shows a flavour profile in the initial phase of chewing gum with menthol/anethol/eucalyptus flavour and with encapsulated extract of black pepper in the coating,

FIG. **13** shows the same in the intermediate phase, and

FIG. **14** shows the same in the end phase.

The scope of the invention will appear from the detailed description below. However, it should be understood that the detailed description and the specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the invention will become apparent for those skilled in the art from the detailed description.

DETAILED DESCRIPTION OF THE INVENTION

The active substances are selected among flavours, acids, salts, high potent sweeteners, and functional substances.

Aromas, which may be incorporated into the chewing gum according to the invention, are selected among natural, naturally identical or synthetic flavours, as well as plant extracts. Examples of applicable flavours are for example peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, and fruit flavours such as orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry, raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavour, etc.

The plant extracts which may be applied instead of or together with one or more of the above-mentioned flavour(s) are preferably selected among extracts of liquorice, coffee, tea, herbs such as sage, thyme, basil, bergamot, balm, valerian, camomile, lavender, aloe vera, and spices such as pepper, cinnamon, *capsicum*, paprika, tarragon, fennel, mustard, dill, caraway, parsley, tomato, etc.

The use of plant extracts in coated chewing gum provides the possibility of preparing novel combinations of flavour and new flavour experiences.

In a preferred embodiment of the invention the active substance(s) is/are a natural vegetable flavouring agent such as fruit and herbs. Accordingly the substance may be selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple, strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, pineapple, grapes, banana, cranberry, blueberry, black currant, red currant, gooseberry, and lingonberry, thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus and mixtures thereof.

It is furthermore an advantage that the natural flavouring agent is dried. A dried agent may have a more intense flavour and may further increase the stability of the flavour because many of the notes of the taste are still present in the more or less intact cells of the fruit or herb. The limited content of water is also an important factor with respect to stability.

In a further aspect, the water content of the natural flavouring agent is less than 75% by weight, such as less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%. However, in situations where a less water content is desired (for stabilty reasons or with respect to have an increased flavour sensation), the water content of the natural flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5–7%, more preferred between 2–6%.

In a preferred embodiment, the natural flavouring agent is freeze-dried.

The natural flavouring agent in solid form may be in the form of a powder, slices or pieces, or combinations thereof. When a natural vegetable flavour is used, it is generally accepted or even desired that a feeling of small pieces of the flavour agent be recognised by the consumer in the chewing process. Accordingly, the natural flavouring agent may be in a form where the particle size is up to 3 mm or even more. However smaller pieces are preferred and in a further aspect, the particle size is less than 3 mm, such as less than 2 mm, more preferred less than 1 mm, calculated as the longest dimension of the particle.

In other situations it may be an advantage to have different sizes of the particles and an example is wherein the natural flavouring agent is in a form where the particle size is from about 3μ to 2 mm, such as from 4μ to 1 mm. However, the skilled person may select any combination dependent on the desired final properties of the coated chewing gum.

As seeds from fruits may have a special flavour, the natural flavouring agent may comprise seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which seeds are substantially intact.

In a still further aspect of the invention, the natural vegetable flavouring agent also provides the gum formulation with natural colour. With seeds of a vegetable or fruit flavouring agents such as strawberry and/or orange, it has been possible to obtain a marbling colouring of the chewing gum as well as a uniform colouring. Accordingly, in a further aspect of the invention, the active substance in solid form may be a colouring agent.

Various acids may also be applied as active substances, such as citric acid, matic acid, tartaric acid, lactic acid, and ascorbic acid or any other acid allowed in food and which is suitable. These may most conveniently be applied together with chewing gum with fruit flavour in order to obtain an improved freshness during the first phase of the chewing period.

Furthermore, according to the invention, instead of or together with one or more of the above-mentioned active substance(s), salts may be applied, such as sodium chloride,

potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide. Hereby an improved chewing gum taste during the initial chewing period is obtained, and in case of sodium bicarbonate and carbamide also an improved dental care effect.

In order to obtain a sweet taste during the initial chewing period, together with or instead of one or more of the above-mentioned active substance(s) sweeteners may be incorporated in the coating, preferably highly potent sweeteners. Especially suitable sweeteners are e.g. aspartame, acesulfame K, saccharin, cyclamate, neohespiridine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucrolase, and alitame.

Finally, in order to obtain a specific effect together with or instead of one or more of the above-mentioned active substance(s), one or more functional substance(s) can be incorporated in the coating such as vitamins and nutrients, "cooling agents", flavour enhancers, enzymes, agents for care and treatment of the oral cavity, antiseptic agents, pharmaceuticals and herbal medicine.

"Cooling agents" and flavour enhancers are substances manufactured by so-called "flavour houses", and which substances are also known as "flavour enhancer", "cooling flavour", "physcol", "optacool", and the like. They are applied in order to make the taste stronger and fresh.

Examples of cooling agents are e.g. lactic acid menthyl ester, disclosed in EP 0794169 A1, mono menthylsuccinate, and salts thereof, disclosed in WO97/07771, and 4-(1-menthoxymenthyl)-2-phenyl-1.3-dioxolan and derivatives thereof, disclosed in U.S. Pat. No. 5,545,424.

Among the vitamins and the nutrients that may be incorporated in the chewing gum according to the invention special mention can be made, without limitation, of the vitamins A, B_1, B_2, B_5, B_6, B_{12}, D_3, E, K, folic acid, niacin, biotin, β-carotene, ascorbic acid, and salts thereof, amino acids, glycerophosphates, minerals in the form of salts, complexes and compounds containing calcium, phosphorus, magnesium, iron, zinc, copper, iodine, manganese, chromium, selenium, molybdenum, potassium, sodium, or cobalt and ubiquinon.

Among agents for the care and treatment of the oral cavity, special mention may be made of hydrogen peroxide, carbamide and carbamide releasing compounds, CPP (caseinphosphopeptide), fluorine compounds such as sodium fluoride, sodium monofluorophosphate, and stannofluoride, arginine, zinc compounds, strontium chloride and potassium nitrate.

Among antiseptic agents, special mention may be made of guanidine and biguanidine, such as chlorhexidine acetate, quaternary ammonium compounds such as benzalkonium chloride, cetylpyridinium chloride, and cetrimide, phenols such as tymol, triclosan, parachlorophenol, and cresol, hexachlorophan as well as salicylanilide compounds.

Enzymes may also be incorporated in the chewing gum according to the invention, e.g. papain, trypsin, amyloglucosidase, lactase, glucooxidase, streptokinase, streptodornase, dextranase, and mutanase.

Among pharmaceuticals, special mention may be made of caffeine, salicylic acid, and derivatives thereof, such as acetylsalicylic acid, choline salicylate, and magnesium salicylate, paracetamol, salts of pentazocine, buprenorphine, and buprenorphine hydrochloride, codeine hydrochloride and phosphate, morphine and salts thereof, methadone hydrochloride, ketobemidone, β blockers, calcium antagonists, verapamil hydrochloride, verapamil, nifedipine, nitroglycerin, erythrityl tetranitrate, strychnine and salts thereof, lidocaine, tetracaine hydrochloride, etorphine hydrochloride, atropine, insulin, alfa-amylase, polypeptides such as oxytocin, gonadorelin, and LHRH, desmopressin acetate (DDAVP), isoxsuprine hydrochloride, ergotamine compounds, chloroquine phosphate and sulfate, isosorbide, demoxytocin, heparin, lupeol, sucralfate and salts thereof, nicotine and salts and derivatives thereof, lobeline, cinnarizine, dimenhydrinate, difenhydramine, cyclizine, scopolamine, miconazole, nystatin, metronidazole, hydrocortisone, astemizole, benzocaine, glibenglamide, onsaedantronum, acyclovir, sumatriptan, tropisetron, pizotifen, cisapride, domperidone, itraconazole, omeprazole, terfenadine, fluconazole, naratriptan, zolmiriptan, rizatriptan, eletriptan, almotriptan, sildenafil, tolfenamic acid, tramadol, cetirzine, and loratidine.

Among herbal medicine special mention may be of *ginkgo biloba*, ginseng, saw palmetto, stevia, ginger, propolis, *echinacea*, St. John's Wort, Siberian ginseng, guarana, and garlic in the form of drugs, extracts or in purified form.

Furthermore, it is possible by means of the present invention to add substances, which cannot resist the thermal and mechanical influences that normally occur during the manufacturing of cores of chewing gum, such substances being certain vitamins, enzymes, and pharmaceuticals.

The active substance(s) is/are added in the form of dry active substance, preferably spray-dried active substance, or in the form of encapsulated active substance. In a preferred embodiment of the present invention, the active substance is present in an encapsulated form. The active substance is preferably present in the form of a powder with particles having a size of 3–300 μm.

The use of encapsulated active substance provides a larger stability of the substance, and the active substance migrates very slowly to the surface of the coated chewing gum. Furthermore, the contact of the encapsulated active substances with the air is limited, whereby possible oxidation processes take place very slowly. The latter are of particular significance in connection with flavours, especially in the form of ethereal oils, such as peppermint, lemon, lime, and orange.

In addition, by encapsulating the active substance, it is achieved that its reaction with other substances is prevented, substances like e.g. sodium bicarbonate with acid and aspartame with aldehyde-containing flavours, and especially in case of substances with an unpleasant taste, e.g. certain pharmaceuticals, the taste may be camouflaged.

In addition, it has been found that by chewing chewing gum that is coated with encapsulated flavour, not only a strong taste explosion is achieved, but also an enhanced taste in all chewing phases. The latter is due to the fact that flavour capsules from the coating layer of the chewing gum are opened both during the initial chewing and in following chewing period.

Furthermore, using an encapsulated active substance may prevent a discoloration of the coating, e.g. plant extracts such as thyme or black pepper. Finally, it may be desirable to prevent water-solubility, e.g. in connection with the use of acids and salts as the active substance.

When an encapsulated active substance is used, conventionally used encapsulation agents are used as the encapsulation agent, for instance, but without limitation, fatty substances, waxes, gelatin, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate (PVA), polyethylene (PE), casein, zein, B cyclodextrine, silica, yeast cells, and a mixture of the above encapsulation agents. Preferred encapsulation agents comprise fatty substances such as hydrogenated soy bean, cottonseed, coconut, sunflower, palm kernel, rapeseed, and *ricinus* oil, or waxes such

as bees' wax, candelilla wax, carnauba wax, paraffin wax, and polyethylene wax, etc. Especially preferred is the use of a mixture of hydrogenated rape oil and carnauba wax.

Encapsulated flavour and methods for encapsulation are known from, e.g., EP 0 170 752 A2, EP 0 453 397 A1, EP 0 455 598 B1, and U.S. Pat. No. 4,386,106.

In a particularly preferred embodiment of the coated chewing gum according to the present invention, the coating also comprises besides the coating material as well as one or more active substance(s) in solid form, one or more liquid active substance(s). This provides a larger flexibility of the process of chewing gum manufacture, and, when encapsulated active substance is concerned, a reduction in costs, since the encapsulation makes the process more expensive, and it is thus reserved for only the most sensitive active substances.

In one embodiment of the invention, the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof, preferably an aqueous solution of saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharin, cyclamate, thaffine, and neohespiridine.

The coating suspension is applied in approx. 2 to 90 increment(s), preferably in approx. 30–60 increments to achieve a uniform coating with a suitable thickness.

The active substance(s) is/are applied by sprinkling or by blowing the substances into the rotating kettles a number of times such as from 1 to 10 times between the dosages of the coating suspension, preferably approx. 1 to 4 times to achieve a suitable effect.

The following is a general description of the preparation of chewing gum.

Preparation of Chewing Gum

The preparation process comprises the following:

Mixing of conventional chewing gum components in kneading kettles (mixers) with strong horizontally placed Z-shaped arms, which processes the raw materials and produces a homogeneous gum mass.

The kneading kettles are heated to a temperature of 30–80° C., typically approx. 45° C. The mixing process starts with gum base quantities that have been weighed out, and the processing of these lasts for 1 20 minutes, typically approx. 10 minutes. Then one or more sweetener(s) in powder form or in liquid form is/are added. The dosage of sweeteners and the following processing last from 1 to 20 minutes, typically approx. 7 minutes.

Then the flavours and the remaining components are added and kneaded for a further 1 to 10 minutes, typically approx. 5 minutes. The admixture of flavours and the remaining components may also take place in the beginning of the kneading process, i.e. before the admixture of the sweeteners. It is also possible to add flavours in two or more portions during the kneading process.

When the kneading is completed, the kneading kettle is tipped, and the gum mass is taken out into carts, onto trays or the like.

The next process is the forming of the chewing gum. Before the forming can take place, the chewing gum mass, however, must be cooled. When taken out, the chewing gum mass has a temperature of 50–70° C., and in order to form the chewing gum, the temperature must be reduced to 30–45° C. The cooling of the chewing gum either takes place by storing the chewing gum mass in carts or on trays for quite a long time or by transporting a thin chewing gum carpet through a cooling tunnel.

The forming of the chewing gum may take place by extrusion through a specially formed nozzle, or the chewing gum may be formed after extrusion by means of rollers, punching machines, tentering wheels, and the like.

The chewing gum may be formed into cores, sticks, balls, cubes, cylinders, and many other shapes.

In order to prevent the chewing gum from sticking to the rollers and other tools, the chewing gum is frequently powdered with a powder, which may consist of i.a. icing sugar, talc, corn flour, and the like.

The formed chewing gum can be cooled immediately to room temperature in a cooling tunnel and be packed (especially in case of bubble gum and soft bubble gum), or the cooling may take place on trays at the store for semimanufactured products at a controlled temperature and moisture.

The formed and cooled chewing gum is then treated by means coating and polishing processes before the packing.

Coating and Polishing of Cores of Chewing Gum

The coating of cores takes place in tilted, round or horizontally placed cylindrical coating kettles that rotate during the whole process. The coating kettles are made from copper, stainless steel or fiberglass-reinforced polyester, and are often equipped with a piping system that supplies and exhausts air and doses the coating suspension.

The coating process may take place as follows:

Cores of chewing gut into movement in rotating coating kettles are added to the coating suspension in small portions that disperse evenly over the surfaces of the cores after a short or long smoothing out time. (The smoothing out time is the period of time during which the suspension disperses over the cores, approx. 10–90 seconds, preferably approx. 30–60 seconds). Afterwards the cores are dried by means of air. The operation is repeated up to 90 times, preferably approx. 30–40 times, until the cores are completely covered and have the preferred measure and the preferred weight.

In order to ease the coating process of chewing gum, a suspension is used which is heated up to 90° C., preferable up to about 75° C., and air which is heated up to at least 35° C. such as about 40° C.

Between the dosages of the coating suspension, one or more active substances) in solid form is/are added in one or more increment(s) in order to provide the chewing gum with a fast effect, e.g. flavour release during the chewing. It is an important aspect of the invention that the drying period is extended to after applying the active substances. When the active substances are added just after the coating process is completed, the coating suspension is still soft and the active substances may be more or less embedded in the coating in the solid form. The skilled person will be able to estimate or to establish by a simple test when the active substance should be added for obtaining a sufficient adherence of the active ingredient to the coating.

As appears from the Examples, the drying period is 0 seconds, however, drying periods up to 50 seconds such as up to 25 seconds are within the present invention and even longer periods may be acceptable depending on the drying properties of the coating suspension, the particle size of the active substance as well as whether it is desired that the active substance should be fully embedded in the coating or should form a superficial layer on the coating.

Furthermore, between the dosages of the coating suspension and the addition of one or more active substance(s) in solid form, one or more active substance(s) in liquid form may be added.

In order to achieve a neat and smooth surface of the chewing gum tablets with the completed coating, these may subsequently be subjected to a polishing. The polishing also takes place in rotating coating kettles in which a polishing suspension or a polishing powder is added to the coated cores in one or more portion(s). The polishing suspension often consists of wax, emulsifier, shellac, gum arabic, water,

etc. The polishing powder often consists of wax only, or of wax mixed with emulsifier, gum arabic or talc, etc.

The present invention is further illustrated below by means of some examples.

EXAMPLES

As a starting point, partly sugar-containing, partly sugar-free cores of chewing gum are used which are rolled out into sheets by means of stamping rollers, i.e. coherent sheets of cores of chewing gum which have a weight of approx. 0.9 g/piece.

A coating kettle DRIA 1200, supplied by Driam Metallprodukt GmbH, Germany, is used for the coating of the above-mentioned cores. DRIA 1200 is a horizontally placed and cylindrical kettle intended for the coating of 50 kg of chewing gum cores. The equipment has computer controlling of the amount of dosages of liquid and solid substances as well as controlling of the smoothing out times, the drying times, air quantities, the temperature of the drying air, and the airflow direction. For dosage of an active substance in a solid form, a pneumatic conveyor having a dispersing arm which ensures an even dispersion of the powder over all the tablets. The coating kettle can be set at various velocities from 1 to 15 rpm.

During the coating process, 50 kg of chewing gum cores are filled into the coating kettle that can be set to a rotation of 8 rpm. During this rotation, the cores of chewing gum are separated from each other. Drying air is applied to the equipment, and surplus talc, which has been added during the rolling out of the cores of chewing gum, is removed. This separation and blowing through of air last for approx. 5 minutes.

Then the rotation speed of the coating kettle is increased to 11 rpm, and the first dosage of the coating suspension may take place.

It is also possible to use small (2 kg) or large (100 kg) tilted, round coating kettles and sprinkle active substance in solid form manually in 1–10 increment(s) between the dosages of the coating suspension. Dosage of active substance in more increments ensures an even dispersion of the powder over all the cores of chewing gum.

For the coating of sugar-containing cores of chewing gum, a saccharose suspension was used in the following examples, and a sorbitol suspension was used for the coating of sugar-free cores.

In the following embodiments, the coating suspension had the following composition:

1. Saccharose suspension	
Sugar juice (70%)	94.45%
Water	4.68%
Gelatine (Bloom value 120–160)	0.87%
Total	100.00%
2. Sorbitol suspension	
Sorbitol liquid/neosorb 70/02	97.86%
Water	1.59%
Titanium dioxide	0.55%
Total	100.00%

The Examples 1, 2, and 3, shows conventional coating of sugar-containing and sugar-free cores of chewing gum, respectively.

Example 1

Coating in DRIA 1200 equipment of 50 kg of sugar-containing chewing gum cores with peppermint taste.

Saccharose suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1–2	500	45	300	11
3–12	900	45	400	11
13	600 + 222*	60	400	11
14–15	700	0	380	11
16–21	1000	0	380	11
22–34	1000	30	410	11
35–38	600	260	280	11
39	500	1500	290	11
40	wax powder 50 g	300	300	8

*A 600 g saccharose suspension + 222 g peppermint oil.

Example 2

Coating in DRIA 1200 equipment of 50 kg of sugar-free chewing gum cores with peppermint taste.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1–2	400	0	250	11
3–5	700	15	300	11
6	700 + 200*	60	300	11
7–16	700	45	300	11
17–24	1000	45	350	11
25–26	700	240	240	11
27	wax powder 50 g	360	360	8

*A 700 g sorbitol suspension + 200 g peppermint oil.

Example 3

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and acetiol.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15–16	20	5	120	50
17–22	30	60	120	50
23–26	40	30	120	50
27–33	30	60	120	50
34–35	20	120	240	50
36	wax powder 2 g	300	300	50

*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

Example 4

Coating in DRIA 1200 equipment of 50 kg sugar-containing chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Saccharose suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1–2	500	45	300	11
3–12	900	45	400	11
13	400	10	0	11
14	400*powder	60	0	11
15–16	700	0	380	11
17	400	10	0	11
18	400*powder	60	0	11
19–20	700	0	380	11
21–24	1000	0	380	11
25–37	1000	30	410	11
38–41	700	260	280	11
42	500	1500	290	11
43	wax powder 50 g	300	300	8

*A powder with a flavour concentration of 28%.

Example 5

Coating in DRIA 1200 equipment of 50 kg sugar-free chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1–2	400	0	250	11
3–5	700	15	300	11
6	350	10	0	11
7	360*powder	60	0	11
8–9	700	10	300	11
10	350	10	0	11
11	360*powder	60	0	11
12–13	700	10	300	11
14–18	700	45	300	11
19–26	1000	45	350	11
27–28	700	240	240	11
29	wax powder 50 g	360	360	8

*A powder with a flavour concentration of 28%.

Example 6

Coating in tilted round kettles of 2 kg sugar-free chewing gum cores with peppermint oil encapsulated in silica.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	17**powder	40	0	50

-continued

Coating in tilted round kettles of 2 kg sugar-free chewing gum cores with peppermint oil encapsulated in silica.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
15–16	20	5	120	50
17–19	30	60	120	50
20 28	40	30	120	50
29–33	30	60	120	50
34–35	20	120	240	50
36	wax powder 2 g	300	300	50

*A sorbitol suspension with 2.75% aspartame.
**A powder with a flavour concentration of 50%.

Example 7

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with peppermint oil encapsulated in gelatine.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	17**powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	20	10	0	50
20	17**powder	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A sorbitol suspension with 2.75% aspartame.
**A powder with a flavour concentration of 25%.

Example 8

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	40**powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50

-continued

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
19	20	10	0	50
20	40**powder	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A sorbitol suspension with 3.75% aspartame, and 7.5% acesulfame K.
**A powder with a flavour concentration of 24.5%.

Example 9

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	20**powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	20	10	0	50
20	20**powder	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.
**A powder with a flavour concentration of 24.5%.

Example 10

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol, as well as menthol encapsulated in gum arabic.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50

-continued

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol, as well as menthol encapsulated in gum arabic.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	20	10	0	50
20	7**powder	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.
**A powder with a flavour concentration of 80%.

Example 11

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, anethol, as well as ammonium chloride encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15	20	5	120	50
16–17	30	60	120	50
18	20	10	0	50
19	40**powder	40	0	50
20–21	20	5	120	50
22	20	10	0	50
23	40**powder	40	0	50
24–25	20	5	120	50
26–27	30	60	120	50
28–30	40	30	120	50
31–37	30	60	120	50
38–39	20	120	240	50
40	wax powder 2 g	300	300	50

*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.
**A powder with a ammonium chloride concentration of 30%.

Example 12

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally extract of black pepper encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20*powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21–22	20	5	120	50
23 24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A powder of naturally extract of black pepper in a concentration of 20%.

Example 13

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powered anise as well as naturally basil extract encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20*powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A powder of naturally basil extract in a concentration of 14%.

Example 14

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally thyme extract encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20*powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21–22	20	5	120	50
23–24	30	60	120	50
25–28	40	30	120	50
29–35	30	60	120	50
36–37	20	120	240	50
38	wax powder 2 g	300	300	50

*A powder of naturally thyme extract in a concentration of 15%.

Example 15

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, lemon, and mango) as well as citric acid encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	30**powder	40	0	50
15–16	20	5	120	50
17	20	10	0	50
18	30**powder	40	0	50
19–20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23–24	20	5	120	50
25–26	30	60	120	50
27–30	40	30	120	50
31–37	30	60	120	50
39–40	20	120	240	50
41	wax powder 2 g	300	300	50

*A sorbitol suspension with 7.5% aspartame.
**Encapsulated citric acid in a concentration of 35%.

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Example 16

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as ascorbic acid encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	30**powder	40	0	50
15–16	20	5	120	50
17	20	10	0	50
18	30**powder	40	0	50
19–20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23–24	20	5	120	50
25–26	30	60	120	50
27–30	40	30	120	50
31–37	30	60	120	50
39–40	20	120	240	50
41	wax powder 2 g	300	300	50

*A sorbitol suspension with 7.5% aspartame.
**Encapsulated ascorbic acid in a concentration of 60%.

Example 17

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, lemon, and mango) as well as cooling agent encapsulated in gum arabic.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	20**powder	40	0	50
15–16	20	5	120	50
17	20	10	0	50
18	20	40	0	50
19–20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23–24	20	5	120	50
25–26	30	60	120	50
27–30	40	30	120	50
31–37	30	60	120	50
39–40	20	120	240	50
41	wax powder 2 g	300	300	50

*A sorbitol suspension with 7.5% aspartame.
**Encapsulated cooling agent, "Cooling Flavouring Powder" from International Flavours and Fragrances, Ltd., England, in a concentration of 20%.

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Example 18

Coating in tilted kettles of 2 kg sugar-free chewing gum cores with a mixture of liquid flavours (apple and cinnamon) as well as aspartame encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Dryiag time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4–9	30	30	90	50
10–11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	25*powder	40	0	50
15–16	20	5	120	50
17–18	30	60	120	50
19	6.6 liquid flavour	10	0	50
20	20	10	0	50
21–22	20	40	120	50
23–24	30	5	120	50
25–28	30	30	120	50
29–35	20	60	120	50
36–37	30	120	240	50
38	wax powder 2 g	300	300	50

*Encapsulated aspartame in a concentration of 10%.

Test Results

A number of sensory tests were carried out as documentation of the achieved effect by the use of active substances in solid form in the coating of a coated chewing gum.

The tests were carried out with 5 to 8 trained tasters per test. The coated chewing gum was served in tasteless plastic cups coded with a randomised three-figure number. There was a 3-minute-break between each product tested, and each product was tested twice.

The tests were carried out partly in the form of a measurement of the flavour release as a function of time (time intensity tests), in which the products were tested after 5, 15, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180, 240, 300, 420, and 540 seconds, partly in the form of determination of a taste profile, in which the products were tested in intervals; the initial phase: 0–1 minute, the intermediate phase 1–3 minute(s), and the end phase 3–4 minutes.

Test 1

A measurement was carried out of the flavour release as a function of time from a chewing gum coated according to Example 8, i.e. with a mixture of eucalyptus, menthol, and anethol encapsulated in fat and wax. The flavour release from this chewing gum was compared with a chewing gum coated according to Example 3, i.e. with liquid eucalyptus, menthol, and anethol. The result of the test appears from FIG. 1 which shows that the use of encapsulated flavour in the coating layer partly results in an extremely high taste onset (taste explosion) during the first 60 seconds, and partly enhances the taste in all chewing phases.

Test 2

In this test, measurement of the flavour release as a function of time by the use of the same amount of eucalyptus/menthol/anethol flavour in liquid form (Example 3) and encapsulated in fat and wax (Example 9), respectively, was carried out. The result of the test appears from FIG. 2, which shows that the use of active substance in solid form provides

a strong taste explosion in the initial phase, and a significantly enhanced effect in the first 4–5 minutes can be observed.

Test 3

In this test, the effect of addition of menthol encapsulated in gum arabic to the coating of a chewing gum coated with liquid eucalyptus, menthol, and anethol, cf. Example 10, was examined and compared with a chewing gum coated according to Example 3, i.e. only with liquid eucalyptus, menthol, and anethol.

The result of the test is shown in FIG. 3 which shows that addition of encapsulated menthol causes a strong taste explosion in the initial phase and an enhanced taste effect in all the chewing phases.

Test 4

A stability test was carried out of a chewing gum coated in accordance with Example 18, i.e. coated with apple/cinnamon flavour as well as aspartame encapsulated in fat and wax. By way of comparison, a corresponding chewing gum in which the aspartame was non-encapsulated was tested.

The result of the test is shown in FIG. 4 which shows that the chewing gum containing non-encapsulated aspartame loses its stability already after approx. 30 days after coating since it develops a bitter taste. The lack of stability is probably due to a reaction between aspartame and aldehyde-containing flavours. In a corresponding chewing gum with encapsulated aspartame in the coating no change in the taste is observed even after 90 days.

Thus, encapsulation of aspartame has a strong stability-improving effect

Test 5

A test was carried out with chewing gum coated according to Example 15, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as citric acid encapsulated in fat and wax in order to determine the taste profile in the initial phase. By way of comparison, a taste profile was recorded for a corresponding chewing gum coated with the same fruit flavours (orange, lemon, and mango), but without encapsulated citric acid in the coating layer. The result of the test is shown in FIG. 5.

As will be apparent, a chewing gum with citric acid has a larger taste intensity and stronger citric notes than a corresponding product without citric acid.

Test 6

A test was carried out in order to determine the taste profile in the initial phase, the intermediate phase, and the end phase, respectively, of a chewing gum coated according to Example 17, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) and with and without cooling flavour encapsulated in gum arabic. The result of the test is shown in FIGS. 6, 7, and 8 which show that the chewing gum with the cooling agent has a larger taste intensity and stronger citric notes in the initial phase. As is apparent from FIGS. 7 and 8, this tendency is maintained in the intermediate phase and in the end phase as well in spite of the fact that the cooling agent was placed in the coating layer only.

Thus, the chewing gum according to the invention shows an increased effect of the active substance in all the chewing phases.

Test 7

In this test the taste profile of a chewing gum coated according to Example 14, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural thyme extract encapsulated in fat and wax, was determined.

The use of encapsulated thyme provides the possibility of developing a chewing gum with an entirely new combination of tastes without having to observe the occurrence of discoloration of the coating layer by the use of liquid extract.

Test 8

In this test the taste profile of a chewing gum coated according to Example 12, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural extract of black pepper encapsulated in fat and wax, was determined. The result of this test is shown in FIGS. 12, 13, and 14. In the same way as in test 7, the possibility of creating new combinations of tastes without discoloration of the coating layer is achieved.

The invention being thus described, it will be obvious that it may be varied in many ways. Such variations are not to be regarded as deviations from the idea and the scope of the invention, and all such modifications as would be obvious to persons skilled in the art, are intended to be included within the scope of the following claims.

The invention claimed is:

1. A coated chewing gum comprising a core of chewing gum and a coating, wherein said coating comprises one or more coating materials and one or more flavor(s), said flavor(s) being in the form of a powder when applied to the coating and at least one flavor is a natural vegetable flavoring agent comprising intact cells of a dried fruit or herb.

2. A method of preparing a coated chewing gum, the method comprising the following steps:

1) providing a core of chewing gum, a coating suspension, and at least one natural vegetable flavoring agent in the form of a dry powder, where said natural vegetable flavoring agent is a powder of a dried fruit or a dried herb,

2) applying the coating suspension onto the core of chewing gum,

3) applying, in one or more increment(s), said at least one natural vegetable flavoring agent onto the coated cores of chewing gum resulting from step 2) said agent being and remaining in the form of a powder throughout said applying step, and optionally repeating steps 2) and 3).

3. The method according to claim 2, wherein the at least one natural vegetable flavoring agent has a water content of less than 75% by weight.

4. The method according to claim 2, wherein the water content of the at least one natural vegetable flavoring agent is less than 15% by weight.

5. The method according to claim 2, wherein the at least one natural vegetable flavoring agent was extracted from one or more vegetables each selected from the group consisting of a coconut, a grape fruit, an orange, a lime, a lemon, a mandarin, a pineapple, a strawberry, a raspberry, a mango, a passion fruit, a kiwi, an apple, a pear, a peach, an apricot, a cherry, a grape, a banana, a cranberry, a blueberry, a black currant, a red currant, a gooseberry, a lingonberry, thyme, a basil, a valerian, a fennel, a parsley, a camomile, a tarragon, a lavender, a dill, a cumin, a bergamot, a sage, an aloe vera, a spearmint, a peppermint, and an eucalyptus.

6. The method according to claim 2, wherein the natural vegetable flavoring agent has been freeze-dried.

7. The method according to claim 2, wherein the at least one natural vegetable flavoring agent is in the form of a powder, said powder comprising a particle having a particle size of at most 3 mm, calculated as the longest dimension of the particle.

8. The method according to claim 2, wherein said powder consists essentially of particles having a particle size from 3 μm to 2 mm, calculated as the longest dimension of the particle.

9. The method according to claim 2, wherein the at least one natural vegetable flavoring agent comprises seed from a fruit.

10. The method according to claim 2, wherein the at least one natural vegetable flavoring agent also provides the gum formulation with natural color.

11. The method according to claim 2, wherein the coating furthermore comprises a flavor selected from the group consisting of peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry, raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavor.

12. The method of claim 2, wherein the coating furthermore comprises an active substance selected from the group consisting of a high potency sweetener and an acid.

13. The method according to claim 12, wherein said active substance is in the form of a powder when applied to the coating.

14. The method according to claim 12, wherein the acid is selected from the group consisting of a citric acid, a malic acid, a tartaric acid, a lactic acid, and an ascorbic acid.

15. The method according to claim 12, wherein the high potency sweetener is selected from the group consisting of aspartame, acesulfame K, saccharin, cyclamate, neohesiridine, thaumatin, glycyrrhizin, monellin, sucrolase, and alitame.

16. The method according to claim 2, wherein the coating furthermore comprises at least one functional substance, each selected from the group consisting of vitamins, cooling agents and flavor enhancers.

17. The method according to claim 16, wherein the at least one functional substance is in the form of a powder when applied to the coating.

18. The method according to claim 12, wherein the active substance is in an encapsulated form when applied to the coating.

19. The method according to claim 18, wherein the encapsulated active substance is encapsulated in one or more material(s) each selected from the group consisting of fatty substances, waxes, gelatine, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate, polyethylene, casein, zein, B cyclodextrine, silica, and yeast cells.

20. The method according to claim 2, wherein the coating furthermore comprises one or more active substances(s), incorporated into the coating while in liquid form, each of said one or more active substance(s) being selected from the group consisting of a flavor, a high potency sweetener and an acid.

21. The method according to claim 2, wherein the coating furthermore comprises at least one salt.

22. The method according to claim 21, wherein each salt is selected from the group consisting of sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.

23. The method according to claim 2, wherein the coating suspension comprises an aqueous solution, said aqueous solution comprising a component selected from the group consisting of a sugar, a sugar alcohol, an artificial sweetener or a mixture thereof.

24. The method according to claim 2, wherein the coating suspension comprises an aqueous solution of one or more constituent(s) selected from the group consisting of saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharine, cyclamate, taline, and neohespiridine.

25. The method according to claim 2, wherein the coating suspension is applied in 2 to 90 increments.

26. The method according to claim 2, wherein the flavoring agent is applied to the coating in 1 to 10 increment(s) between the dosages of the coating suspension.

27. The method of claim 2 wherein, during step 3), the natural vegetable flavoring agent is embedded, in the coating, in solid form.

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